**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION**

This document relates to:

*The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*
Case No. 1:18-op-45090 (N.D. Ohio)

*The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al*.
Case No. 1:17-op-45004 (N.D. Ohio)

**MDL No. 2804**
**Case No. 17-md-2804**
**Judge Dan Aaron Polster**

**DECLARATION OF KELLY A. MOORE IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON PREEMPTION BY PHARMACY DEFENDANTS, ABDC, CARDINAL, AND MCKESSON**

I, Kelly A. Moore, declare as follows:

1. I am a partner at the law firm of Morgan, Lewis & Bockius LLP and counsel to Defendant Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center.

2. I make this declaration to place before the Court certain materials relied on in the Motion for Summary Judgment on Preemption by Pharmacy Defendants, ABDC, Cardinal, and McKesson.

3. Attached as **Exhibit A** is a true and correct copy of excerpts from the transcript of the deposition of Kyle Wright, which was held on February 28, 2019 in the above-captioned case.

4. Attached as **Exhibit B** is a true and correct copy of excerpts of the deposition of Demetra Ashley, which was held on March 15, 2019 in the above-captioned case.

5. Attached as **Exhibit C** is a true and correct copy of Exhibit 14 from the deposition of Thomas Prevoznik, which was held on April 17, 2019 in the above-captioned case.

6. Attached as **Exhibit D** is a true and correct copy of excerpts of the expert report of James Rafalski, which was submitted on behalf of the Plaintiffs in the above-captioned case.

7. I declare under penalty of perjury that the foregoing is true and correct.

Executed this 28th day of June, 2019.

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# Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

| | |
|---|---|
| IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION | MDL No. 2804<br>Case No. 17-md-2804 |
| This document relates to: | Judge Dan Aaron Polster |

The County of Cuyahoga v. Purdue Pharma, L.P., et al.
Case No. 17-OP-45005

City of Cleveland, Ohio vs. Purdue Pharma, L.P., et al.
Case No. 18-OP-45132

The County of Summit, Ohio, et al. v. Purdue Pharma, L.P., et al.
Case No. 18-OP-45090

VOLUME I

Videotaped Deposition of Kyle J. Wright

Washington, D.C.

February 28, 2019

9:33 a.m.

Reported by: Bonnie L. Russo
Job No. 3244302

them?

MR. SHKOLNIK: Objection.

THE WITNESS: As long as it's being prescribed in medical necessity. That's the only way I can answer that.

BY MR. STEPHENS:

Q. Okay. And would you also agree that chronic pain is a serious problem for many Americans?

MR. MIGLIORI: Objection.

THE WITNESS: I can't answer that.

BY MR. STEPHENS:

Q. Would you agree that DEA has a duty to ensure that there's no interference with the distribution of controlled substances to the American public in accordance with the sound judgment of their physicians?

MR. MIGLIORI: Objection.

MR. SHKOLNIK: Objection. Outside the scope of what he's here to testify.

MR. BENNETT: I will also object to form and remind the witness of the limits of his authorization.

THE WITNESS: Would you repeat the question, please.

BY MR. STEPHENS:

Q. Sure.

The question was DEA has a duty to ensure that there's no interference with the distribution of controlled substances to the American public in accordance with the sound judgment of their physicians.

A. The DEA is responsible to make sure that the -- there's a legitimate supply and that supply is protected.

Q. Right.

And that's actually a statutory obligation, correct?

A. Correct.

Q. In Title 21.

A. Correct.

Q. Okay. All right. So, Mr. Wright, you've testified at length today about the distributor initiative. And I'm certainly not going to cover all the ground that's been covered.

A. Thank you.

Q. But -- but there -- there are a couple of things that I still want to go through with you. Okay.

# Exhibit B

IN THE UNITED STATES DISTRICT COURT
NORTHEASTERN DISTRICT OF OHIO
EASTERN DIVISION

| | |
|---|---|
| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION | MDL No. 2804 |
| This document relates to: | Case No. 17-md-2804 |
| The County of Cuyahoga v. Purdue Pharma, L.P., et al., Case No. 18-OP-45090 | Judge Dan Aaron Polster |
| City of Cleveland, Ohio vs. Purdue Pharma, L.P., et al. Case No. 18-OP-45132 | |
| The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 1:18-OP-45004 (N.D. Ohio) | |

The videotaped deposition of DEMETRA ASHLEY, called for examination pursuant to the Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, taken at 10 South Wacker Drive, Suite 4000, Chicago, Illinois, on the 15th day of March, 2019, at the hour of 9:16 a.m.

Reported by: Gina M. Luordo, CSR, RPR, CRR
License No.: 084-004143

page that's titled Mission, do you see that?

A. Yes.

Q. It says the mission of the Office of Diversion Control is to prevent, detect and investigate the diversion of pharmaceutical controlled substances and listed chemicals for legitimate channels of distribution while ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical commercial and scientific needs.

Do you see that?

A. Yes.

Q. Did I read that correctly?

A. Yes.

Q. And is that, as of November 14, 2014, what you personally understood to be the mission of the Office of Diversion Control?

A. Yes.

Q. Now, when Ms. Zolner was asking you some questions a few minutes ago about that Martinsville pharmacy, you made a reference to the mission of the Office of Diversion Control?

A. Yes.

Q. Is this Page 2 of Exhibit 25 the same mission you were referring to there?

A. Yes.

Q. Will you agree, based on your 35 years of experience at the DEA, that what the Office of Diversion Control is attempting to do is, on one hand, minimize the amount of diversion that occurs while at the same time ensuring that folks who need opioids or other controlled substance can get them?

A. I agree with that.

Q. Would you also agree that to the extent that diversion efforts are, I think to use your words, arbitrary, which I think was the term you used in connection with the Martinsville Pharmacy testimony. To the extent that the efforts at diversion control are increased, that could have an effect of making opioids available to fewer folks who need them?

MR. SHKOLNIK: Objection to form.

MS. BACCHUS: I'm going to object to form.

MR. SHKOLNIK: And personal opinion.

THE WITNESS: Yeah, it's my personal opinion, but I do not agree that they are restrictive enough that it wouldn't allow for persons to get controlled substances if they need it.

BY MR. SCHUTTE:

Q. Perhaps I misunderstood your testimony

# Exhibit C

# EXAMINING THE GROWING PROBLEMS OF PRESCRIPTION DRUG AND HEROIN ABUSE

## HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

APRIL 29, 2014

**Serial No. 113–140**

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Mr. BURGESS. The gentleman yields back. I thank the gentleman for his testimony.

We will now hear from the members for questions, 5 minutes for each member.

I will begin.

Well, Mr. Rannazzisi, you just gave some rather startling statistics. Mr. Botticelli, you said in your testimony we can't arrest our way out of this problem. So let me just ask you, from a federal perspective, we have put a lot of money and a lot of effort on behalf of taxpayers into this, what is it about this that is not working?

Mr. Botticelli, we will start with you, and maybe we can just go down the line and just answer the question, how has this become the problem that it is?

Mr. BOTTICELLI. Sure. I think a number of my Federal panelists have articulated some of the problems, and I think, first and foremost, a lot of this issue is driven by the vast overprescribing of prescription pain medication. A recent report by the GAO showed that the vast majority of physicians get little to no training in substance use disorders and little to no training in safe opioid prescribing. And a part of our——

Mr. BURGESS. Let me stop you there because this is not a new problem. I mean this was a problem 40 years ago when I was in medical school, and I would disagree with the statement that we got no training, but OK, the training may not be adequate to the scope of the problem, but honestly, can we say that this is something that just happened to us, and we were completely unaware that this was an issue? I mean how could you possibly make a statement like that?

Mr. BOTTICELLI. I think part of what the balance has been, and I think it has been out of kilter, is that physicians, quite honestly, were pushed in terms of making sure that we adequately treated pain in the United States. And we absolutely need to make sure that we do that. I think we need to have a balanced strategy that understands the tremendous addiction potential of these drugs, the risky patients that we have before us in terms of who should be prescribed prescription medication, as well as monitoring those who are developing a problem.

So I do think that this is a balanced approach in terms of both making sure that we are adequately treating pain, but we are also not inadvertently creating a problem by overprescribing these medications to people who are developing a problem, or who are at risk.

Mr. BURGESS. I don't want to put words in his mouth, but Mr. Rannazzisi seemed to imply that we are overprescribing. Is that a fair assessment of your testimony?

Mr. RANNAZZISI. I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing. Actually, they are prescribing illegally, they are not overprescribing, they are illegally prescribing.

So, yes, if you are considering that overprescribing, yes.

Mr. BURGESS. Well, that is your job. You are law enforcement, so you get to close them down, right?

Mr. RANNAZZISI. And we are trying. They are overwhelming us with numbers.

Mr. BURGESS. All right, I do want everyone's response to that because in the interests of time and wanting to keep to the 5-minute interval, I am going to submit that in writing to each of you.

I want to bring up something because each—or several of you have brought it up, and that is the issue of making naloxone much more available. Maybe we should also be talking about making Ambu bags available for people who are going to overdose. I mean it is hard to know who is going to overdose, but, Mr. Botticelli, you brought it up, and I think, Dr. Sosin, you brought it up as well, but what is the issue here with making this available?

Mr. BOTTICELLI. I think that we have been tremendously heartened, both at the Federal level, as Dr. Volkow talked about, in terms of the approval of new delivery devices for doing that. One of the main areas that ONDCP has been working with our state partners is the passage of state legislation to look at naloxone distribution. And so I think we have now 17 states that have enacted naloxone distribution legislation, which I think has really been helpful here.

We have also been, quite honestly, working with many law enforcement agencies across the state——

Mr. BURGESS. Pardon me for a moment. It is a federally controlled substance, is it not? Naloxone?

Mr. BOTTICELLI. It is not a controlled substance, if I remember correctly.

Mr. BURGESS. OK. Is there a cost issue?

Mr. BOTTICELLI. There is a cost issue, and one of the things, Chairman, that you asked is what are the opportunities that we have in terms of looking at this, and again, I think it was really helpful that SAMHSA looked at how we might use existing Federal funds, but I think if there is an area that we can continue to explore together it is how we might enhance resources for many overdose prevention efforts.

One of the things that I have heard as I have traveled around the country is that having state legislation and having these devices is a great start, but many states and local areas are underresourced in terms of implementing it.

Mr. BURGESS. Yes, and again, I may submit that in—for answer in writing as well, but, Dr. Volkow, let me just ask you. You mentioned in your testimony to address this problem, we have to recognize the special character of this phenomenon, and part of which is that opiates play a key role in relieving suffering. So as providers and policymakers, are we doing a good job of walking this line?

Dr. VOLKOW. Based on the numbers, I don't think we can say we are, and the reality is that in this country, we have both an undertreatment of pain and over-prescription of medications. These are not exclusive. And one of the issues that we have been faced with, and Mr. Botticelli had been discussing is, in 2000, when the Joint Committee for Accreditation of Hospital demanded that you treat pain, you see a steep increase in the number of prescriptions. So what you are doing in parallel, there has not been an increase in education in medical schools. So each 7 hours average in the

United States there is a diversity of opiate medications that are currently available, and there are many indications where actually patients are being given the opioids when it is not severe pain, and this, for example, is the case in many cases for young people with dentists that are prescribing the opiate medication, so there is a room for improvement on that education of providers.

The other issue too that we have not understood very much when we were—I mean certainly, when I was in medical school, they will tell you if you prescribe an opioid medication with someone that is suffering from pain, they are not going to become addicted. Now, we can come to recognize that it is not the case, that there are patients that are taking the medication as prescribed, and they can become addicted. So the issue is who are they, how do we recognize them so we can prevent that transition. And——

Mr. BURGESS. Well, and my time has expired. I will just offer the observation, 40 years ago, I was given the admonition by a professor in anesthesiology, this stuff is so good, don't even try it once. So clearly, it was known 40 years ago.

I recognize Mr. Welch for 5 minutes for questions please.

Mr. WELCH. OK, I want to thank the panel and the Chairman as well.

You know, in Vermont, as I mentioned in my opening statement, we are just trying to face this directly, which is, I think, a much better approach than denial, and it has engaged the community in some very effective ways. And it has developed—I think it has helped our providers develop what they call a Hub and Spoke System where there is an emphasis on medication, which really does seem to be helping some folks who are willing to be helped, and then some wraparound treatment services for people who can benefit by that. And a lot of our ability to do that is because we are getting some federal help. We get about $6 million out of the Substance Abuse Prevention and Treatment Block Grant. That has been level funded. And my question really to Mr. Clark, can you explain the decision, I guess this is the Administration decision not to propose an increase in that program, given the intensity of the crisis. And I think with this discussion occurring all around the country, obviously, you are going to have many more states that are willing to roll up their sleeves and try to get engaged, which would suggest the resource need is there in order to help make this successful.

Dr. Clark?

Dr. CLARK. Mr. Welch, we are working very closely with state authorities, with organizations like NASADAD and NASMHPD to address these issues, but we also, as Mr. Botticelli pointed out, are approaching this from a comprehensive approach rather than simply using a single funding mechanism to address the issue. We need to keep in mind that we need multiple strategies to address this problem, and with those multiple strategies, we believe that we can make an impact. So relying, indeed, on the Affordable Care Act and other strategies, we can leverage the Block Grant Funding to target this.

We are also allowing jurisdictions to prioritize using our prevention efforts, as well as our treatment efforts. The problems that they are experiencing——

Mr. WELCH. All right.

Dr. CLARK [continuing]. In their respective jurisdictions——

Mr. WELCH. OK, thank you. No—but no more money. Money is tight, I get it.

And, Mr. Botticelli, your predecessor came up and had a great visit with us in Vermont. It was tremendous to have him there. And we have expanded the use of naloxone—how do you say that?

Mr. BOTTICELLI. Naloxone.

Mr. WELCH. Naloxone. Yes, and we have had some success with that. We have had a number of instances of it being used successfully just recently about 15 times.

But do you think that the FDA should consider making that an over-the-counter medication?

Mr. BOTTICELLI. Yes. So, first of all, like you, I really want to applaud you and Governor Shumlin in terms of calling significant attention to this issue. I spent the better part of my career in Massachusetts, and am very familiar with——

Mr. WELCH. Right.

Mr. BOTTICELLI [continuing]. The heroin issue that we have had in New England for a long, long time.

Our office, as part of our prescription drug abuse plan and overdose, has been looking for continued ways to expand the use of naloxone. Again, I think we are heartened by this delivery device. Our partners at NIDA are looking at and researching the expansion of and use of other ways. So we are having conversations with both Federal partners and, quite honestly, some external stakeholders who are really, really interested in terms of looking at how do we increase the—not only the availability of naloxone, but continue to promote easier to use and, quite honestly——

Mr. WELCH. OK.

Mr. BOTTICELLI [continuing]. Perhaps some cheaper versions of——

Mr. WELCH. Right.

Mr. BOTTICELLI [continuing]. Naloxone.

Mr. WELCH. I have time for one more question.

Dr. Volkow, I want to ask you about this issue with doctors and with patients. I have known close friends who have had serious medical issues and have been in a lot of pain, and once that line is crossed where they are getting the prescription medication, it almost seems like there is an undertow where the answer to the pain question always is essentially to get more medication and more powerful medication. And a patient in that moment is pretty vulnerable. And the doctor gets really persistent advocacy by the patient and sometimes the patient's family. You have got to do something. So how do we help the doctors deal with what, Dr. Burgess, of course, we have another doctor here, but how do they, there are a lot of doctors around here, but how do we—the doctors really have to be on the frontline, and it is very tough because they have a patient who is in pain, they have a family who is saying will you do something, but the something that is getting done in many cases is resulting in long-term problems.

Dr. VOLKOW. Yes, and you are touching on one of the hardest issues to deal with clinically: how do you manage severe chronic pain. What many people don't know is that the risk of suicide for

patients with chronic pain is double that of the general population, so it is extraordinarily debilitating. And the strongest medication we have are opioids. The problem with opioids, apart from addictiveness, is that you become tolerant very rapidly, and so that requires that you increase the dose. So chronically, and then you have to shift to something more potent, and that is exactly where the whole problem lies around. They are not ideal, but it is what we have, and it can relieve the patients in the moment that they need them.

The strategy is what other alternatives we can use other than just relying as—in opioids as the only alternative, and that is where research is ongoing to see—that is what I was mentioning in the whole area of brain neuroscience, the feasibility of devices that can actually be used potentially to handle and manage pain will be a breakthrough. You will rely less on medications. And I also think the aspect of we as a society have created the expectation that anything that is wrong with you should be treated with a medication. So zero tolerance for pain. And I think that as a culture, we need to revision that also.

Mr. WELCH. Thank you.

I yield back. Thank you very much.

Mr. GINGREY [presiding]. Thank you. Thank you, Mr. Welch.

And I am sitting in, obviously, for Dr. Burgess. Let me just make a brief statement, and then I will ask my question.

As a physician of many years, I don't think that even back in the day we were given the proper training in regard to pain medication. Also I will say this, there has been a lot of emphasis over the past 10 years or so about advanced directives and the necessity for that, and, of course, the hospice programs that have developed and that sort of thing, but I don't hear hardly any discussion about patients given their wishes in regard to how they want their pain controlled in a terminal situation where there is no chance for recovery. I don't know that people really understand, and in many instances pain medication is started because the family members don't want their loved one to suffer. That is quite natural and appropriate, but before you know it, the patient has gone beyond the stage where they can say, look, I don't want to be totally zonked out at the time of my demise. So that is just, I guess, food for thought in a way.

I am going to ask my specific question, Mr. Rannazzisi. You said earlier in your testimony that the DEA is just getting overwhelmed by all these rogue pain clinics that are popping up everywhere. How is that happening? How do these places just pop up, as you put it, and why is it happening, why are you getting overwhelmed?

Mr. RANNAZZISI. Well, that is a great question, sir. It is not just DEA that is overwhelmed. Our state and local counterparts are overwhelmed. Think about this. Prior to the Ryan Haight Act, the Internet drug bill that was passed, there were, say, seven clinics—pain clinics in Broward County, in 2010 there were 142 clinics in Broward County. Now, if you look, when we moved our enforcement groups down there, and we moved 10 tactical diversion squads to work with our state and local counterparts, and we started knocking off these rogue pain clinics, they moved up into Georgia. If you looked at the 75 corridor, there were over 100 pain clin-

ics going up that 75 corridor. Some of them were right off of the interstate. You just get off and get back on. Then they moved into Tennessee. Tennessee now has approximately 300 clinics.

Now, if you think that—state and local law enforcement and DEA doesn't have the capacity to go after every one of these clinics quickly, because these are legal drugs that they are peddling, and we have to establish that that doctor is prescribing outside the usual course of professional practice, and not for legitimate medical purposes. It takes time. These cases take time. So what they are doing is they are just counting on the fact that they are going to run the clinic that is not being hit by DEA. So we are all overwhelmed, everyone in law enforcement.

Mr. GINGREY. Yes, but what percentage would you say of these clinics are fraudulent?

Mr. RANNAZZISI. In Florida, the vast majority of them. In Georgia, I believe that the vast majority of those clinics that popped up were. There are good pain clinics, don't get me wrong. Every pain clinic is not bad.

Mr. GINGREY. Yes.

Mr. RANNAZZISI. But the pain clinics that we are looking at are absolutely atrocious. There is no medical care.

Mr. GINGREY. Yes.

Mr. RANNAZZISI. It is the modern-day crack house.

Mr. GINGREY. Thank you for that answer.

And any of you could answer this. Last year, GAO, the Government Accountability Office, found an overlap in 59 of the 76 programs it identified in the drug abuse and prevention area. What steps are any of your agencies taking to minimize overlap and more efficiently spend out taxpayer dollars? I mean you would think that we could get some efficiency here. Anybody?

Mr. BOTTICELLI. Sure, Chairman. Our office has looked at that report and has been working with our Federal partners to look at the breadth of our prevention programs, and to make sure that we are not, quite honestly, duplicating programs.

I do think that, however, if you talk to many, many people at the local level, they will tell you, however, that we don't have enough prevention, and I think you heard from many, many folks up here that while we may have programs that are addressing the same issue, they are reaching not the entirety of the population. So we really want to make sure that, one, that we are not kind of duplicating the programs that we have already——

Mr. GINGREY. Well, very important, I would think that you guys are talking to each other, of course. Others? I have a little time left, 2 seconds, 1 second. Wait a minute, I am the chair now, aren't I? I have 5 minutes left. Mr. Clark?

Dr. CLARK. Well, as——

Mr. GINGREY. Dr. Clark, excuse me.

Dr. CLARK. One of the things we are concerned about in the Administration is the issue of fragmentation, overlap, and duplication, and that we do work very closely with our federal partners to make sure that we minimize fragmentation, overlap, and duplication. And working under the assistance of ONDCP, we are able to address that.

As was pointed out, communities need multiple resources, and you find that sometimes you cannot completely eliminate some overlap because, indeed, the unique issues of individual communities require that there be some overlap, but we are very sensitive to both the GAO concerns and OMB's concerns about fragmentation, overlap, and duplication, and assiduously try to avoid that.

Mr. GINGREY. Thank you all. I thank the panel. My time has expired, and I yield 5 minutes now to Mr. Lujan.

Mr. LUJAN. Mr. Chairman, Doctor, thank you so very much for the time today, and I am glad to see that we are having this hearing. This is important. By the chairman and the committee staff acknowledging that this hearing needed to take place, I think we are acknowledging there is a problem across the country.

The question after this hearing today though is, are we going to sweep this under the rug again, or are we going to do something significant with recommendations that are going to come from experts?

This is a problem plaguing America. The case in New York brought more attention to what was happening with heroin abuse and overdoses, but we have been losing lives across the country for years. And what are we going to do? There are recommendations that have been put on the table by many experts. It has been studied over and over and over. There is a program from 2011 on the prescription drug side to reduce abuse significantly over 5 years, I will be asking the question where are we with that, but every life that is lost as a result of this is one life too many.

There are only so many parts of the world that are growing poppies. Do we not know, as the United States of America, where poppies are being grown and how they are migrating into the United States in the form of heroin and illegal substances? Seems to me we should. And what are we doing to stop that flow? That is very troubling.

Now, going back to the prescription drug side, there have been presentations that we have seen in New Mexico that have been put together by some people that I respect very much, that show a correlation with drug overdoses with increased prescriptions that are coming out, not just pain medication facilities that are popping up. And so one of the questions that I have is, is there data that is reported to any of you that you do analysis on, where there is a court—at least with the data that I have seen, there is—it is shown that there is a correlation between overdoses and increased prescriptions that are being administered, and what do we do with that data? Are we able to go in or is that an area where we don't have enough support now between the federal and the state partners? And I would ask anyone that would like to tackle that.

Dr. SOSIN. Thank you, Congressman Lujan.

You mentioned a New Mexico report. Dr. Paulozzi from CDC worked with scientists in New Mexico and health department staff there to analyze and demonstrate those relationships, and absolutely, there is a very tight relationship between the volume of opioid prescribing and opioid overdose deaths. That information does get used at a national level, and thinking about the areas to intervene, but also at the state and local level where it has to be, to better understand how the problems in each individual jurisdic-

tion, and the factors that are influencing the prescribing practices are being addressed there.

One of the ways that CDC in particular works is by trying to liberate data by working with state and local health departments to understand the context of prescribing, of health system data, and of mortality data, to put a better picture and understand the context within which overdose deaths are occurring and abuse is occurring, and then be able to target programs like through their PDMP's, like restriction programs, et cetera, that address those problems.

Dr. VOLKOW. If I may, first of all, I want to thank you for bringing up that issue because the way that I view it, this is an urgent issue and we cannot put it under the rug, under no conditions. And I feel passionate because I do get the parents coming to me and say when we went to wake up our child, it was dead, and we didn't even know that they were abusing opioids.

The other issue is that we do have the tools to actually address the problem of opioid prescription abuse and opioid deaths. We need to implement them. We have treatments that work for drug addiction that can decrease the number of overdoses, but also we need to address the problem that we have with chronic pain in this country. How many people suffer chronic pain in this country? Estimated IOM, 100 million. 100 million. There is the notion on that 100—that there is an increase in chronic pain, and that needs to be addressed. So from the healthcare perspective, we need to address it.

Mr. LUJAN. And, Dr. Volkow, as my time expires, there are some questions that I will be submitting in to the record, but I would welcome your response as well.

And, Mr. Chairman, I just wanted to share with you that there is a program in New Mexico that appears to be working with the distribution of Narcon, where there has been a reversal of more than 250 overdoses last year, where they are getting it into the hands of first responders and nurses. So it is not necessarily on the street, but it is with those that are responding to these accidents. And there may be a way for us to work on that with some ideas down the road.

Mr. Chairman, again, I share, before you return to the hearing, how much we appreciate that you are doing this and you have brought this hearing, but I certainly hope that there is more that will be done, and that this hearing won't be the last of hearings and conversations, and an approach that we can take as a Congress to work with our state partners to do something. This is a bad problem across the country, but it is also plaguing New Mexico. And I thank you for your attention to this, Mr. Chairman.

Mr. BURGESS. The Chair thanks the gentleman, and does also observe that further hearings are likely to be necessary, and as Mr. Welch pointed out, to hear from governors, and I would like to hear from some of our mayors because they are on the first lines of this battle.

The Chair now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions please.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you to our panel for being here today, addressing this very important issue.

I would like to start by asking a question of Mr. Botticelli and Dr. Volkow.

Understanding the path of addiction, there is, and I think you have both identified a genetic basis for that, one of the things I would like to know is, again, the progression. Is this something that starts with tobacco use, smoking, use of alcohol, drinking, and then how does it progress and how do you feel? And I will just start with you, Mr. Botticelli, and then have Dr. Volkow comment.

Mr. BOTTICELLI. I do have to acknowledge that just about everything that this field knows about this has come from the work of Dr. Volkow.

Clearly, we know that there is a genetic predisposition for many people in terms of family history of substance abuse, but we also know that there is, like many diseases, there are environmental factors that go into that issue.

We know that substance use disorders are a disease of early onset, so that many people who do develop, left untreated, left undiagnosed, develop a substance use disorder, largely because of starting alcohol, tobacco and/or marijuana use——

Mrs. ELLMERS. Yes.

Mr. BOTTICELLI. At a very young age. Clearly, there are some particular issues as it relates to the addiction potential of prescription drug medication——

Mrs. ELLMERS. Yes. Yes.

Mr. BOTTICELLI [continuing]. But the vast majority of people that, at least, I have talked to, and the data show that those folks who do have a significant opioid use disorder have started from a very young age. And if you saw the Philip Seymour Hoffman story, he actually started with alcohol abuse at a very young age. So we know that there are prevention and intervention opportunities that we can have along the way to really make sure that we are identifying people early in their disease progression, and then we are intervening in this issue.

Mrs. ELLMERS. Yes.

Mr. BOTTICELLI. The other piece that you talked about, and again, I think it still warrants further work, is what about the progression from prescription drug use to heroin addiction.

Mrs. ELLMERS. Yes.

Mr. BOTTICELLI. Clearly, we know that it is a progressive disease, and people, left untreated, will often progress to more significantly harmful use patterns, but we also know that price plays a role, as the DEA mentioned, in terms of the progression. So we know that there are multiple factors that really affect peoples' progression, not only in terms of overall development of a substance use disorder, but from prescription medication to heroin.

Mrs. ELLMERS. Yes. Yes. Dr. Volkow?

Dr. VOLKOW. Yes, and the questions you ask intrigue many scientists, and it is called—has led to the term of gateway——

Mrs. ELLMERS. Right.

Dr. VOLKOW [continuing]. Hypothesis because all of the epidemiological studies have repeated corroborated that most individuals that become addicted to illicit substances started with nicotine or alcohol, then transition into marijuana and then the other drugs.

So the question is that just because it is more accessible that you start with nicotine or alcohol——

Mrs. ELLMERS. Yes.

Dr. VOLKOW [continuing]. Or could it be that these drugs, including nicotine, alcohol, and marijuana, are changing your brain in such a way that it makes it more receptive to the addictiveness of drugs.

Mrs. ELLMERS. Yes.

Dr. VOLKOW. And there is data now from genetic studies and from studies in animals that suggest, at least for the case of nicotine and alcohol, and also marijuana, that it is changing the sensitivity of the brain reward sequence in a way that primes you——

Mrs. ELLMERS. Yes.

Dr. VOLKOW [continuing]. To the addictiveness of these other drugs. And in the case of prescription opioids, that is also what they are observing, that most of the individuals that end up addicted to prescription opioids had a history of nicotine addiction earlier, or had started abusing alcohol.

Mrs. ELLMERS. Yes. Thank you.

My last question is for Mr. Rannazzisi. Obviously, your agency is working with many other agencies on this issue, and I am going to ask you a question that really falls under the FDA, but from your opinion, in the work that you are doing, do you believe that some of the prescription drugs, the deterrent formulas such as, you know, for Oxycontin, some of the deterrent formulas, will that make a difference and is it feasible that if we take this approach, that that is going to help on the wide and broad scope that you have outlined if we are using these deterrent forms?

Mr. RANNAZZISI. Absolutely. The abuse deterrent formulations will make a difference. But those drugs will still be abused——

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. Orally with a potentiator, like a muscle relaxer, or a Benzo, but in the end, it is going to stop them from crushing and snorting, or crushing and injecting.

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI. And we know that when you crush and inject, or crush and snort, you are raising the risk——

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. Of overdose and death——

Mrs. ELLMERS. Yes. Yes.

Mr. RANNAZZISI [continuing]. Just in that method of delivery. So, yes, do I think it is important? Absolutely, it is important. Look at what happened with the Oxycontin product, when it went from the OC to OP, you could bang that tablet with a hammer and it is not going to break.

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI. It balls up in your nose when you try to snort it. It is crazy——

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. That, if you try to abuse that drug, but what do we see everybody doing? Immediately, they started moving to the Oxymorphone product——

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI [continuing]. Or the immediate release Oxy 30s. OK, so they are adapting.

Mrs. ELLMERS. Yes.

Mr. RANNAZZISI. If we could figure a way to get an abuse deterrent formulation across the board, then we are going to see some significant results——

Mrs. ELLMERS. Thank you.

Mr. RANNAZZISI [continuing]. Absolutely.

Mrs. ELLMERS. Thank you so much for your answers, and your insight on this issue.

And, Mr. Chairman, I yield back the remainder of my time.

Mr. BURGESS. Gentlelady yields back.

The gentleman from Kentucky, Mr. Yarmuth, recognized 5 minutes for your questions please.

Mr. YARMUTH. Thank you very much, Mr. Chairman. And I thank the panel as well for the testimony, and for what is obviously a very committed effort across the spectrum of government to deal with this problem. I am glad to know that, I shouldn't say glad, but it is somewhat reassuring to know that this is not just a Kentucky problem. Certainly, in my travels in my district and around the state, and talking with law enforcement and with mental health professionals, and everyone who is involved in this area, we have a huge problem in Kentucky. During the first 3 quarters of 2013 there were at least 170 Kentuckians who died from heroin overdoses, and that was 41 more people who had died the entire previous year, and is actually a 200-plus percent increase since 2011. So we have a problem that is there and growing.

And one of the young people who died was the nephew of a Kentucky state representative, Joni Jenkins, a good friend of mine and a great representative. Her nephew, Wes, they suspected, began with prescription drugs and then moved to heroin because of expense. He died in May of 2013. And she told her story in the Louisville Courier-Journal, and I would like to read one of the things she said because it prompts a question. She said, for an entire year, our family kept the addiction private. They were well aware of it, he had been in and out of treatment and they were working with him, but they kept it private so Wes would not suffer the social stigma of being a drug addict. I now know that there is a terrible shame attached to this illness, but we have to break through the silence to find a cure. And she said, I also know that I will search for answers the rest of my life for that.

Is this a problem that you have seen? You are nodding your head, Mr. Botticelli, so respond to that, that much of the the access to treatment or the willingness to treatment is deterred because of a social stigma?

Mr. BOTTICELLI. I have—and many of us have heard that story countless times from parents. Many of us were just in Atlanta with a conference sponsored by Chairman Rogers. And we hear that story repeatedly, and I think our collective efforts have really been to raise the visibility of ensuring that people know that addiction is a disease, and this is not about shame, this is not about guilt. We know that one of the reasons why people don't seek treatment, and why parents don't ask for help, is because of the shame and embarrassment that is related to that. And so part of what I think

all of our Federal partners are doing is how do we raise the understanding and visibility, and, quite honestly, the compassionate treatment of people with addiction—of addictive disorders into this work. And I think that we are seeing, quite honestly, a movement in terms of—like we did with other disorders that were shameful and stigmatized——

Mr. YARMUTH. Yes.

Mr. BOTTICELLI [continuing]. That we have to elevate the voice of parents and people in recovery so that we do know that hope is possible, and that it would be easier for them to come forward and ask for help, but unfortunately, we have heard that story way too many times from——

Mr. YARMUTH. Yes.

Mr. BOTTICELLI [continuing]. From parents and people who are affected.

Mr. YARMUTH. Have you come up with any great answers? I mean what can we do to help that just as individual members? We do span the country anyway.

Mr. BOTTICELLI. Yes. I think there are a couple of things that we are doing. A lot of our work at the Office of National Drug Control Policy, we actually established an Office of Recovery to really promote the fact—we are looking at the development of recovery support services, so that people in the community can see that recovery is possible. I think we have been promoting—those of us who are in recovery, talking very publicly about the fact that we are in recovery, because it shows to other people that this is not just about death and destruction, that there really is hope on the other side of this. So I think all of us play a role in terms of destigmatizing that.

Just having these hearings really shows the fact that we have leadership in this country who are concerned about this, and it is not a shame. This is not a moral choice, this is not a moral failing, this is about a disease, and we have to deal with it from a public health perspective.

Mr. YARMUTH. Yes.

Mr. BOTTICELLI. So I really appreciate your acknowledgement of that—those challenges.

Mr. YARMUTH. Well, it seems to me that much of this problem involves education. I assume that when these young people, or whether it is young or not, but predominantly young people begin on prescription drugs, they have no idea that this is the course that they could likely be on. And I don't know whether that is a school issue, a PTA issue, what it is, but it seems to me like information is one of the greatest avenues for combatting this problem.

Well, anyway, Mr. Chairman, I would request unanimous consent that this OpEd that I mentioned from Joni Jenkins be made a part of the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. YARMUTH. Thank you, and I yield back.

Mr. BURGESS. The gentleman yields back his time.

The Chair now recognizes the gentleman from Ohio, Mr. Johnson, 5 minutes for your questions please.

Mr. JOHNSON. Thank you, Mr. Chairman, and I really appreciate the opportunity to hear from the panel today on this very, very important issue.

You know, prescription drug and heroin abuse are very serious—is a very serious epidemic in Ohio, and parts of my district in eastern and southeastern Ohio are some of the worst hit.

In 2012, 5 Ohioans died every day from unintentional drug overdose with opioids, both prescription and heroin, as the driving factor. Attorney General Mike DeWine identified heroin as contributing to as many as 11 fatal overdoses a week. It is a major public health crisis. However, prescription opioids continue to be the lead contributor to fatal overdoses in the state. In 2012, for example, an average of 67 doses of opioids were dispensed for every Ohio resident.

Law makers, nonprofit organizations, medical, industry leaders, communities and parents across the state have been working to coordinate their response to this epidemic, but in a corner of Ohio that shares borders with 3 other states, communities are struggling to get drug abuse under control. Individuals identified as abusing in one state may cross state lines to escape detection and abuse in another. A nonintegrated system also makes it harder to identify prescribing providers and pill mills.

So for all of you on the panel, anyone that wants to try and respond to this, I realize that states are largely in charge of implementing their own prescription drug monitoring programs, but in multistate areas like I serve, the importance of working together to curb abuse cannot be emphasized enough. So what is being done at the federal level to encourage states to share information compiled by their respective PDMPs?

Mr. BOTTICELLI. Thank you, Congressman, and as you have articulated, both the establishment of vibrant prescription drug monitoring programs, and, quite honestly, the interstate interoperability of those programs, has been key for much of the work that we have been doing on the Federal level. So, we are happy that in 2006 we only had about 20 operable prescription drug monitoring programs in the United States, and now we have 48 that are operable, one in the process and unfortunately, one state that doesn't have a prescription drug monitoring program. And as part of this strategy, we have been working with the Bureau of Justice Assistance and the Boards of Pharmacy to really look at interstate operability so that those states that share a border can make sure that they are sharing data. So now we have 20 states that are able to share information across borders, and clearly, we have a goal of making sure that all of these programs share data among particularly neighboring states.

Mr. JOHNSON. Yes, I will share with you that, as a 30-year IT professional myself, I can tell you that architecture and data standardization, interface standards, those are very, very critical components. If you don't know where you are going, any road will get you there. And it is one thing to have a monitoring system, it is quite something else to have a monitoring system that adheres to standards so that it can be effectively used.

How do we make the nationwide PDMP system more effective, and what still needs to be done to fully achieve a fully-integrated network?

Dr. SOSIN. Congressman Johnson, thank you for your question. Clearly, the PDMP and the ability to achieve successful, effective PDMPs is critical to the law enforcement side, the public health side as well, the clinical side as well. And as Mr. Botticelli commented, we are making progress, meaning that we are better understanding the components of these PDMPs, and what it is that needs to be shared and how to share them. The work that you all are doing in raising visibility, that governors and mayors are doing, saying that this is an issue that they are going to address, also allows this opportunity to set the standards for what we need to share and how we will share that information across borders.

The CDC, working with the FDA and the Bureau of Justice Assistance, has been funding at Brandeis, the prescription behavioral surveillance system, which takes from 20 states the PDMP data they have, to better understand what these factors are that increase the success of PDMP's.

Mr. JOHNSON. Let me get to one more quick question. I have to move quickly.

How can we shift drug abuse prevention efforts from the collection of silo data like we are talking about, to a system in which this information isn't lost every time an individual realizes that they are being tracked, and takes evasive measures like leaving a health plan, for example, because not only do you have working across state lines, but an abuser that goes from one health plan to another can also hide. So how do we solve that problem?

Mr. BOTTICELLI. And some of my colleagues can add on to this, but part of what we have been really trying to focus on is make sure that we are treating and integrating substance use issues as part of mainstream healthcare, of really looking at things like making sure that people are getting screened and intervened as part of their overall health plan so that, you know, for a very, very long time, we have had two systems of care in the United States. We have had medical care over here and behavioral healthcare over here, and that we haven't necessarily really looked at how we make sure that we are treating substance use disorders as a medical condition.

So part of our goal is more thorough integration of mental health and substance use services within our primary care settings——

Mr. JOHNSON. Sure.

Mr. BOTTICELLI [continuing]. Because it is really important that we not see these as two separate issues.

Mr. JOHNSON. Yes.

Mr. Chairman, I have many, many more questions. Obviously, this is a complex and sensitive issue for many Americans, but I have run out of time so I yield back. Thank you.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back his time.

The Chair recognizes the gentlelady from Florida, Ms. Castor, 5 minutes for your questions please.

Ms. CASTOR. Thank you, Mr. Chairman, and thank you to the panel very much.

This hearing is really hitting home for me today because yesterday I learned that the death of a friend last month was tied to her long-term opioid addiction. Her sister sent me an email, I got it just yesterday, and she committed suicide, and her sister said because of her long-term addiction. So she left a daughter and a husband and an entire family, and the sister is asking please do more. So I hope we can all come together to tackle this. It is causing so much pain for so many families.

And the State of Florida has really been at the heart of the problem. And still in Florida, they say that every 7 to 8—every—I can't believe it, 7 to 8 minutes, someone overdoses in the State of Florida. I am also hearing from my local hospitals. They have had to add rooms in the NICU units of hospitals because of babies being born addicted, and these babies typically will cost $1 million to take care of, and they are in the hospital for a month. So we had better invest in prevention or else we are going to be spending a lot on the outside.

So, Mr. Rannazzisi, Florida—the general talking points are, well, Florida has improved. There was a huge law enforcement crackdown. We have adopted a prescription drug tracking system, the PDMP. The problem is that doctors are not using it. The last statistics I saw, only 3.5 percent of all prescriptions being written are being checked on that database.

What is your view right now in Florida? Have we made progress? What is left to do?

Mr. RANNAZZISI. I think under the leadership of Attorney General Bondi and law enforcement leaders down in Florida, yes, we have made progress, absolutely. The problem is, again, we are overwhelmed by the numbers. There are so many people down there in Florida. We actually have cases where Florida rogue pain clinic operators were funding clinics in northern states, so when when the heat is on them, they are going to move into another state.

I think that we are making progress, but again, it is going to take time. Now, the PDMP issue, I would love to see mandated PDMP use. The National Association of Boards of Pharmacy have gone out of their way to ensure that there is interoperability and interconnectivity between the PDMP's. I think they have 25 states that are already connected, and they have done a phenomenal job, but if no one is looking at that PDMP, or very few are looking at that PDMP, it is not going to help.

Ms. CASTOR. So do you agree that the local law enforcement efforts—what I see on the ground in my community, in the Tampa Bay area, we used to have these long lines with cars from out of state, people waiting outside in the alley for these pill mills to open up. You don't really see that anymore, but with these statistics on the rate of deaths from overdose, something else is happening. We are not really making a dent there. Has it shifted to the internet, are they going out of state, is it both? What is going on?

Mr. RANNAZZISI. I think they are moving to more rural areas where there is less law enforcement presence. I think the operators understand—I have a great video I would have loved to have shown you of a clinic, and what happens as soon as the clinic opens. I think that they are adapting. The clinic owners are adapting very well, and they are one step ahead of us right now, but in

the end, local law enforcement is doing a phenomenal job, and they are moving people out of the Tampa Bay area and out of the 3-county area, but it is still there——

Ms. CASTOR. Yes.

Mr. RANNAZZISI [continuing]. It is just moving to more rural areas where they can't address the problem as quickly.

Ms. CASTOR. So in this very sad e-mail from my friend that I got yesterday, she said she has read now about the FDA approval of Zohydro, pure Hydrocodone, non-tamper resistant, 10 times stronger than Vicodin, the Vicodin prescription opiate. I know that the Advisory Committee to FDA had some very serious concerns with this, yet it has been approved.

Dr. Volkow, could you give me your opinion on whether this drug should be readily available?

Dr. VOLKOW. Well, we clearly have a very large number of opioid medications, and we are overprescribing them. I wouldn't point my finger at one or the other. I do think that the feasibility of getting formulations that cannot be diverted is something that is very powerful, and the FDA should be commended because it came up—pharmaceuticals can come up with an indication for a medication that is deterrent proof, and that is incentivizing to the development of these types of medications.

Zohydro is Hydrocodone, it is slow delivery over 12 hours, and it actually does not have Acetaminophen, and because the way that you have—correctly which is Vicodin, the way that you have it is combined with Acetaminophen which produces liver toxicity, which led the FDA to consider if someone needs Hydrocodone, do you need to give them Acetaminophen, and it was in that context that they approved it——

Ms. CASTOR. And——

Dr. VOLKOW [continuing]. But——

Ms. CASTOR [continuing]. Could I ask, since my time is short, Mr. Botticelli, do you agree with the FDA's approval, or do you have concerns?

Mr. BOTTICELLI. I think the important point, and again, I don't think the FDA has their own process in terms of how they approve medications. I would agree that how we continue to make sure that we have abuse-deterrent formulations is really important. I also think that this really underscores the importance of prescribing, and training on prescribing, because I think the point is that we have many medications that are open for a potential to abuse, and we want to make sure that physicians and other prescribers really understand the risks associated with these drugs.

Ms. CASTOR. And, Mr. Rannazzisi, local law enforcement has expressed concern about this new drug on the street because it is so potent, and because it is likely, if a child takes it, it could death. What is your view?

Mr. RANNAZZISI. Yes, local law enforcement and DEA and our federal partners have all expressed. We all lived through the Oxycontin problem back in the '90's into the 2000's, and we just don't want history to repeat itself. Too many people passed from the abuse, circumventing that delivery system.

Mr. BURGESS. The gentlelady's——

Ms. CASTOR. And my——

Mr. BURGESS [continuing]. Time has expired.

The Chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions please.

Mr. GRIFFITH. Well, let me pick up there. You are concerned about this newer drug, and so my question is what do you all do, and I would ask it of all of you but I start with you, Mr. Rannazzisi.

Mr. RANNAZZISI. Rannazzisi.

Mr. GRIFFITH. Rannazzisi, thank you. And that would be, how do we do a better job of predicting where we are going to see spikes and abuse on drugs as they come forward, because some people say that we should have probably seen the increase in the prescription drug abuse of opioids and heroin?

Mr. RANNAZZISI. Well, we monitor the amount of drug going into a particular state through our ARCOS system, but in the end, what we generally see is the drug being abused in the Appalachian area of the country, and then it spreads out from there. So when we were looking at Oxycontin, for instance, the Oxycontin abuse epidemic started in that area, Kentucky, Tennessee, southern Ohio——

Mr. GRIFFITH. Southwest Virginia.

Mr. RANNAZZISI. Yes, southwest Virginia—well, yes, absolutely. And then spread out. And we believe that pattern is going to happen again with this new product. It is just a matter of time. We know that product is now in the pharmacies and being dispensed, so——

Mr. GRIFFITH. And, now, for the people that we—that you have identified, I think that one of the other speakers said abuse-deterrent formulations. Once we know somebody is abusing, I have always liked the lock-in, where you lock into a pharmacy and you lock into a doctor, because one of the problems in southwest Virginia that you mentioned a minute ago is, is that you can be in West Virginia, Tennessee, Kentucky and North Carolina all within—no matter where you are in southwest Virginia, within an hour or 2 hours, you can be in any one of those states because of the way the geography is, and you can go from one rural area to another.

So what are we doing on that? Are we looking at that as a possible means? Dr. Clark, if you want to answer, that is fine. I am just trying to find answers.

Dr. CLARK. Clearly, there is no simple answer, and your question is a very important one, and this committee is trying to address it. We are working with the Association of State and Territorial Health Offices, and the Federation of State Medical Boards, and the Boards of Pharmacy. We do collect surveillance data from our household survey and working with our colleagues in the CDC, so part of the issue is monitoring the movement of individuals, getting practitioners, whether they are pharmacists, nurse practitioners or physicians, to monitor what it is that they are doing. Getting people to access and actually use the PDMPs, and having interoperability, as was pointed out. So—and then involving community coalitions, because, as was pointed out from the representative from Florida, people know where the places are. And what we need to do is——

Mr. GRIFFITH. Sure.
Dr. CLARK [continuing]. To get community coalitions——
Mr. GRIFFITH. Well, that is why——
Dr. CLARK [continuing]. To carry that information.
Mr. GRIFFITH. That is kind of why I like the lock-in because then, you lock them into a doctor, into a pharmacy, if you know, now, I don't want to do that to folks who haven't been identified as having a problem, but once you know they have a problem, then that gives you a better handle on what they are doing if you lock them in and that is the only place they can go. Wouldn't you agree, and I need to hurry because I have other things I want to ask?
Dr. CLARK. That is one strategy that can be employed. So you want to make sure that if you do that, that they have access to the resources necessary to be in that——
Mr. GRIFFITH. Sure. And here is the dilemma that we have, because one of the things that the DEA is—has done, and we talked about this the last time you were here, is that they are asking the distributors to, you know, say, OK, don't sell so much to a pharmacy if that pharmacy looks like they are above the average, or if you see some sign that they may be abusing. And I told the story about what happened when I went to my local pharmacy, and there were two people in there who were both being told you have to come back next month, which was not a few—but a few days away, because we used up our allotment. And I intuited that maybe they only had 1 supplier, and then that supplier said, he's above average for other people who have more than 1 supplier. I went back and checked and that is exactly what is going on. He didn't know that was the problem, but I said, you only have one supplier, don't you? He said, yes, I use one distributor. And I think that is the problem.
So we have on the one hand, we want to lock out people who are abusing it. On the other hand, we want to make sure people who need it, get it. So I guess what I am saying in the second matter is, for the rural areas, it may be a problem because that is less law enforcement, and we recognize that, and why a lot of my region is in different HIDA designations. At the same time, you want to make sure people are getting the drugs they need, and if you are in a rural area, you are a small pharmacy, you may only be using one distributor. While the DEA doesn't have a quota, the distributor then is putting a quota on because, based on other pharmacies, that particular pharmacist or drugstore is ordering more drugs, but it is because they are only using the one supplier as opposed to using two or three.
How do we solve that problem? And I think Dr. Volkow wants in on this.
Dr. VOLKOW. Yes, I was smiling because the notion is we have situations where a patient cannot get their medication, and yet at the same time, the DEA has to collect this massive amount of pills that people are not using, which tells you we are overprescribing the number of pills that are necessary.
So coming back to the point that we have been discussing, we really need to educate the healthcare system on the optimal way of prescribing them, not just when they need them, but the number of tablets that you are given. I mean all of us have the idea, go to the dentist, 2 weeks of opioid prescriptions. I mean you need one

day. So it is the whole notion of educating the healthcare system, and educating the lay public, and making the responsibility too of—why do we need to provide so many pills. And the insurers can get involved into these type of solutions.

Dr. CLARK. And the lock-in approach works as part of a treatment plan——

Mr. GRIFFITH. That is right.

Dr. CLARK [continuing]. With someone who suffers from chronic pain, the practitioner develops a treatment plan, the patient agrees, and that actually benefits everyone.

Mr. GRIFFITH. Very good.

Mr. BURGESS. The——

Mr. GRIFFITH. I know my time——

Mr. BURGESS. The gentleman's time has expired. We will give an opportunity perhaps for a second round, but I wanted to go to Mr. Griffith because he has been waiting so long.

Mr, GRIFFITH. Absolutely.

Mr. SCALISE. Thank you for that, Mr. Chairman, and for our panelists for this important discussion. I know in my home parish of Jefferson, Louisiana, we have seen spikes in increase of drug-related deaths over the last few years, and each year it just seems to be going up higher. When I talk to my coroner in Jefferson, Gerry Cvitanovich, who works very closely in trying to, of course, they see the end result of it, but they also try to work on the front end in doing some of the education that Dr. Clark has talked about and others. They have seen that heroin is the one that seems to be popping up the most. I think last year, heroin deaths accounted for a majority of all the drug-related deaths, over 100 of those. And in my home parish of Jefferson, like I said, we are seeing this across the board.

One of the things they do work on is just trying to educate people in the community. And I know, Dr. Clark, you have talked about this in your testimony, and alluding to work with not just pharmacists but others.

What are the different things that you have been doing, and if you have had success on the education front, especially not just within the medical community, but within the targeted populations of those folks that might have the highest likelihood of being exposed to heroin?

Dr. CLARK. Again, one of the things, a comprehensive strategy becomes critical, and I talked with prevention, working with community coalitions, so that we have that message. We have already heard about the issue of chronic pain management, and people moving from the use of a prescription opioid to drugs like heroin.

So having good strategies for pain treatment, working with state health and territorial health officers, federation and state medical boards, nursing organizations, dental organizations and even veterinarians, because they, too, have access to prescription——

Mr. SCALISE. Right.

Dr. CLARK [continuing]. Opioids, we can address that end of the agenda, then——

Mr. SCALISE. Yes, I want Mr. Rannazzisi——

Dr. CLARK [continuing]. Probably——

Mr. SCALISE [continuing]. To answer this too because I know you talked about this in your testimony as well, so if you can touch on your experiences there.

Mr. RANNAZZISI. We never turn down the opportunity to go out and speak to professional organizations. We have a very good relationship, or a fine relationship with the National Association of Boards of Pharmacy, the individual pharmacist associations, and the medical associations. When they ask us, we will come out. The Pharmacist Diversion Awareness Conference, we go out and we have been to 14 states, and trained over 6,000 pharmacists in their corresponding responsibility, the trends and trafficking for pharmaceuticals, to make them aware of what is going on so they know how to deal with this when a bad prescription comes in and what they are supposed to do.

We have industry conferences. We bring industry in. October of last year, we brought the distributors in to talk about what we are seeing trendwise, and what they need to do as far as their legal obligations under the Act. We bring the manufacturers and importers in. In April or May of last year, we brought them in. And we do this on a regular basis to show the trends and trafficking. We are out there educating as much as possible because it is one of the pillars in the pharmaceutical initiative that the White House is pushing for.

Mr. SCALISE. One of the things when you talk to the people on the ground, our local, whether it is coroners, law enforcement, there are a lot of different federal programs out there, and I do want to touch on that GAO report because there are some concerning issues that they raised that have been touched on a little bit, but I want to get into a little bit more, but on that front, when you look at all the grants that are out there, I know in Louisiana, I think grants come in from five different departments through thirty different programs for some of these treatment programs. So there is a lot of overlap and duplication, but is there a better way maybe to block grant these, to put them together in a way that would be more flexible? And maybe, Dr. Clark, you can answer, are we giving states enough flexibility today and with the duplication can we do a better job and maybe consolidating those grants in a way that allow the states to do what they do best, without having to go through so many different processes, through so many different agencies, where you have this duplication?

Dr. CLARK. Well, clearly, we have to work with states and their discretion in how to prioritize what it is that they view as important epidemiologically in their jurisdiction. And so we have supported the use of block grant funds to the discretion of the states, and worked with both the individual state authorities and the national organizations associated with that.

We are also working with recovery-oriented organizations so that we have peers, people who are recovering from substance use disorders to help speak up and carry out the message, working with community coalitions and others because, indeed, they can tell a better story than professionals or regulators, et cetera. So——

Mr. SCALISE. OK, and——

Dr. CLARK [continuing]. The——

Mr. SCALISE [continuing]. And let me apologize, my time is about to go, I do want to at least ask for the record, if I can get this information on the GAO report, because it did identify, you have, what, 15 different federal agencies, 76 different federal programs that all have abuse prevention or treatment programs, and they also identified overlap of 59 of the 76 programs. And so I think Dr. Gingrey had earlier asked Mr. Botticelli and Dr. Clark to talk about what your agencies are doing to address that overlap, those problems that were identified in the GAO report.

If, Dr. Sosin, I am sorry, Dr. Volkow and Mr. Rannazzisi can also get me their information to—just to show what you all are doing to try to address the overlap problems that were raised in that GAO report.

And with that, I will——

Mr. BURGESS. Well, the gentleman's time has expired. I think that information will be generally interesting to the committee, so if the committee staff will provide that information to the committee.

Mr. SCALISE. Would you all be OK with getting that to the committee? Thank you.

Mr. BURGESS. And the Chair would recognize the gentleman from Texas, Mr. Green, 5 minutes for your questions please.

Mr. GREEN. Thank you, Mr. Chairman. And I thank the O&I Committee for having this hearing.

Prescription drug abuse is a real growing and public health threat that must be addressed. The consequences of abuse and addiction to opioids such as prescription pain relievers and heroin has a devastating effect on our communities. We need a comprehensive solution that protects public health, preserves patient access to the needed therapies, and improved access to treatment.

Last week, an article was published in the New England Journal of Medicine discussing the Department of Health and Human Services' efforts to address the prescription opioid overdose epidemic, including improving access to the addiction treatment services.

Dr. Volkow, you were one of the authors of this article, and, Dr. Clark and Dr. Sosin, the heads of your respective agencies also authored this article. The article makes clear that the treatment of addiction to prescription drugs and other opioids with proven approaches like Methadone and other medication assisted therapy is of crucial importance. It describes the importance of the Affordable Care Act in increasing access to care for many Americans, including those who are struggling with addiction disorders.

Dr. Volkow, can you elaborate on how the ACA builds on the Mental Health Parity and Addiction Equity Act, and improve on insurance coverage for people who are addicted to prescription drugs, heroin or other substances?

Dr. VOLKOW. Yes, the problem is that, as I mentioned in my testimony, is that less than ⅓ of patients that require, that could benefit from opioid medications, are getting them for the treatment of their addiction. And these reflect, among other things, the fact that many of the people that are addicted to drugs do not have an insurance, and rely on the state funding to get their treatment. And as a result of that, we have removed the healthcare system for a position there—where they could not just act in preventing substance

use disorders, but on treating them. The healthcare act, by providing insurance to those that currently don't have it, will give them the opportunity to be treated in the healthcare system for substance use disorders, as well as, in those instances where the addiction has not occurred, for the healthcare system to intervene in prevention. So that is why it is so important.

Mr. GREEN. Dr. Clark, do you agree with that?

Dr. CLARK. Indeed. When people who present for treatment can't get treatment, are asked why they couldn't get treatment, the largest reason is cost and access to treatment.

Mr. GREEN. OK, thank you. I understand the ACA provision creates an optional Medicaid state plan, benefit for states to establish health homes for the coordination of beneficiaries with chronic conditions, has also supported some states in their effort to address the drug abuse.

Dr. Clark, can you elaborate on how the Health Home Program is beneficial in tackling the problem of abuse?

Dr. CLARK. Well, we have actually, with regard to opioids, we have got several jurisdictions that are looking at health homes as a way of dealing with opioids. So in Vermont, one jurisdiction, I think, Rhode Island, I will have to clarify that, is also taking that approach. Comprehensive services being offered where a person's care is adequately monitored offers us an opportunity to reduce some of the complexities associated with opioid misuse.

Mr. GREEN. Thank you. It is clear from the comments the Affordable Care Act makes it possible for many people with substance use disorders, whether it is addiction to prescription drugs, heroin, or other substances, to access the treatment they so desperately need.

Mr. Chairman, I know we have had our differences over the Affordable Care Act, but I would hope we all share the goal of providing more robust treatment to those who are working to overcome this addiction.

And I yield back my time.

Mr. BURGESS [presiding]. The gentleman yields back. Our discussion with the Affordable Care Act will continue at a later date.

Mr. GREEN. I am sure it will.

Mr. BURGESS. We have now I think heard from all members who wanted to ask a question. I would ask unanimous consent that a follow-up question be allowed for those of us who remain.

Mr. GREEN. I don't have any problem with that. I can't stay, but——

Mr. BURGESS. Very well, but I wanted to get that unanimous consent agreed to before you left, so it is not just on my shoulders.

Mr. GREEN. I trust the Chairman.

Mr. BURGESS. Mr. Griffith, I interrupted you before. Would you like to follow up on your line of questioning?

Mr. GRIFFITH. Well, I would just like to give an opportunity, Mr.——

Mr. RANNAZZISI. Rannazzisi.

Mr. GRIFFITH [continuing]. Rannazzisi.

Mr. RANNAZZISI. Yes.

Mr. GRIFFITH. Thank you. I am sorry I have such a hard time with that this morning. But Mr. Rannazzisi was about to comment

on the dilemma that we have with the small rural pharmacists, or pharmacy, that has one distributor.

Mr. RANNAZZISI. Yes, and I want to thank you for clarifying that DEA has not set a quota downstream for the distributors.

The distributors are working through their issues regarding due diligence to determine if there is a problem pharmacy or if it is not a problem pharmacy. I think that the rural pharmacies present a specific problem because they do need to get medication to their patients, and they need that downstream supply. We are hoping that the distributors are on site, looking at their operations before they completely cut off the distributor, or limit the pharmacy, but again, that is a business practice and, unfortunately, I have no control over their business practices.

Mr. GRIFFITH. Well, and I would just say it is because of the concerns and I am sure some memos have been put out by the DEA, we are all trying to do the right thing, that has caused the distributor to be concerned, and maybe if there could be some acknowledgement from the DEA to the distributors, hey, keep an eye out if it is rogue, but if it is just you are looking at, you know, this pharmacy is more than another pharmacy, find out if they have just one distributor because that makes a huge difference in whether or not they are truly distributing more of the opioids than somebody else. And if you all could do that, that would be greatly appreciated.

Mr. BURGESS. The gentleman yields back. I thank the gentleman for his follow-up.

Dr. Volkow, you made a statement that was really fairly provocative a few moments ago, and I just wanted to follow up on it a little bit with you when you were discussing the effect of nicotine, alcohol on developing—I guess you were talking about developing brains and then you added the—with the addition of marijuana, and I ask you not to say anything about the rightness or wrongness of the public policy, but as you know, this nation is right now engaged in a significant experiment where some states have legalized marijuana. Are you all studying that and the effect of this decriminalization in some states? Are we prepared for what might happen next?

Dr. VOLKOW. Yes, definitely. I know, unfortunately, it is one of those experimental situations that is happening, whether we like it or not. So what we have done is provided, identified the grantees, the researchers, in those communities where there has been legalization for recreational or medical purposes to actually give them supplemental money so that they can look at the consequences of these changes in policy, in the education of systems, in accidents, in emergency room admissions, in productivity in the workforce. We need to have evidence that can then—hopefully can guide policy, as opposed to doing policy in darkness on the beliefs of people, and what—since you brought up the issue, to one of the things that is also a concern as discussing the prescription, people are using prescriptions because they feel that are prescribed by physicians, they cannot be so harmful.

The notion that marijuana has so-called medical purposes is also changing the perception of this drug cannot be so harmful if it has medicinal properties. And the whole perception of risk is changing,

which, again, has opened the willingness of young people to take marijuana and to consume it regularly.

Mr. BURGESS. Well, I do hope that you are monitoring the situation, since society has provided you the experimental situation. I also hope that you are preparing to deal with what the downstream effects are from this rather bold social experiment that some of the states are undertaking right now. And I hope that is more than just sending more money to those states. I hope that it is something that you are—that oversight is happening at your level, that there will be a national monitoring of this.

Dr. VOLKOW. The way that we oversee research protocol is very, very rigorous. If the scientist is not producing or the methodology is not adequate, we do not fund them.

Mr. BURGESS. Just speaking of downstream effects, there is also the issue, and it has been brought up several times this morning, and any of you feel free to comment on this, the issue of, of course, the device by which the drug is administered, and then the possibility for exposure to Hepatitis B or C, or HIV. From a public health perspective, are we preparing ourselves for any differences in the incidence of these illnesses as a consequence of the delivery device?

Mr. BOTTICELLI. I will start on that. One of the main concerns of HHS has been, obviously, the increase in viral hepatitis and hepatitis C among the very young cohort of injection drug users. So we have been working in concert with the Health and Human Services who has put forth actually an action plan to diminish viral hepatitis, and clearly, there is a lot of overlap in terms of the issues that we are talking about here. So this is obviously a significant public health concern, so we want to make sure that we are dealing with this in a concerted way.

Mr. BURGESS. Yes, and, of course, the good news right now is Hepatitis C is one of those things that looks very well like there may be a cure that is not just on the horizon but is here. The only problem is it is very expensive. And my differences with Mr. Green over the Affordable Care Act aside, ultimately though, someone has to pay for that, so I hope we are doing the necessary—I hope we are monitoring and doing the necessary preventive things to keep that in check, and to prevent the disease, rather than just simply now being able to cure it with a very expensive therapy that, thankfully, is available.

Mr. Botticelli, did you have some additional observations on the issue of the states that are legalizing marijuana?

Mr. BOTTICELLI. I do, and what I wanted you to know is that in addition to the additional NIDA grants that are out there, our office has actually convened a group of Federal partners to look at the eight criteria that the Department of Justice has laid out for Colorado and Washington, and are really committed to gathering data on the Federal, state and local level, looking at what is the impact in terms of legalization in Colorado and Washington have on both the public health and public safety consequences that we have. So in addition to some of the public health-related work that Dr. Volkow has funded, we are also looking at what are the public safety consequences, things like increase in drugged driving, interstate transportation of marijuana from Colorado to other states. So

our office has really been committed in terms of ensuring that we have good public health and public safety data to monitor what is happening in Colorado and Washington.

Mr. BURGESS. And, Mr. Rannazzisi, I would assume that your agency is participating in that as well?

Mr. RANNAZZISI. It still is a Schedule I controlled substance. We are still doing investigations concerning marijuana downstream.

Mr. BURGESS. And are you monitoring the downstream effects in neighboring states, in the incidences—as Mr. Botticelli talked about, the incidence of driving while impaired, the incidence of even just crime, are you compiling those statistics so they will be available to policymakers in subsequent hearings?

Mr. RANNAZZISI. We are talking to our state and local counterparts in all of the surrounding states, and we are gathering information. I don't know how all-inclusive that information is because, quite frankly—some of the state and locals are not keeping that type of information, but we are keeping tabs with our state and locals on what is going on within their states.

Mr. BURGESS. Very well.

Mr. GRIFFITH. Mr. Chairman.

Mr. BURGESS. Yes, the Chair recognizes the gentleman from Virginia.

Mr. GRIFFITH. I would be remiss, since we have taken on marijuana, not to mention that I have just introduced a Bill to legalize the use of marijuana in medicinal circumstances, akin to the Virginia plan that was passed in 1979, that requires a doctor's prescription, thus, changing the scheduling. The Bill actually calls for the changing of the scheduling. The DEA is in a tough spot. Some of these states are doing it, but it is still a Schedule I, which means that the DEA has a hard time collecting the data that you just asked for without stumbling across felons that they are not prosecuting. So they are in a catch 22. I think it is much better to have doctors and pharmacists, and the regular system working, because then you get real data for your scientists to look at and see if it is effective, as they designed it to be.

So the Bill doesn't go as far as Colorado or Washington might want it, or the Crazy California Plan as I often call it, but it allows real doctors with real pharmacists and real distributors, controlled by and under the laws of the United States, to use true marijuana if it can be used in a real way medicinally.

Mr. BURGESS. Very good. The gentleman yields back.

I am all for giving doctors more power.

That actually concludes all of the questions that we have from members. I neglected to mention at the start of the hearing, ask unanimous consent that members' written opening statements be introduced into the record. Without objection, the documents will be entered into the record.

In conclusion, I would like to thank all of our witnesses. I will thank the member that have participated in today's hearing. I will remind members they have 10 business days to submit questions for the record, and I will ask the witnesses to all agree to respond promptly to the questions submitted in writing.

With that, the subcommittee is adjourned. Thank you for your attendance today.

# Exhibit D

EXPERT REPORT

# Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

**Prepared by**
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- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to inform decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

## III. Identifying Suspicious Orders Distributed in CT1

I have described in this report the ways in which distributor and manufacturer defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed five suspicious order methodologies, some of which were

utilized by one or more of the defendants. These methodologies are identified in the McCann Report as "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.[110]

### A. Methodology: Maximum Monthly, Trailing 6 Month Threshold

**Cuyahoga County: 1996-2018**

| Distributor | Flagged Orders of Oxycodone (Dosage Units) | Flagged Orders of Hydrocodone (Dosage Units) |
|---|---|---|
| AmerisourceBergen Drug (p. 46) | 50,578,040 (86.5% of total dosage units) | 24,412,050 (92.7% of total dosage units) |
| Cardinal (p. 91) | 92,257,585 (96.6% of total dosage units) | 29,954,990 (93.6% of total dosage units) |
| McKesson Corporation (p. 136) | 49,621,330 (92.0% of total dosage units) | 21,298,200 (87.1% of total dosage units) |
| CVS (p. 181) | 0 shipped | 43,763,460 (95.7% of total dosage units) |
| Walgreens (p. 236) | 40,776,500 (95.3% of total dosage units) | 34,718,901 (95.1% of total dosage units) |

**Summit County: 1996-2018**

| Distributor | Flagged Orders of Oxycodone (Dosage Units) | Flagged Orders of Hydrocodone (Dosage Units) |
|---|---|---|
| AmerisourceBergen Drug (p. 676) | 35,909,640 (89.4% of total dosage units) | 23,505,340 (89.3% of total dosage units) |
| Cardinal (p. 721) | 52,594,125 (92.7% of total dosage units) | 19,029,900 (90.4% of total dosage units) |
| McKesson Corporation (p. 766) | 41,057,500 (90.9% of total dosage units) | 21,299,480 (86.9% of total dosage units) |
| CVS (p. 811) | 0 shipped | 26,734,980 (94.0% of total dosage units) |
| Walgreens (p. 236) | 16,833,800 (95.7% of total dosage units) | 22,166,224 (95.1% of total dosage units) |

[110] I utilized these Defendants: Cardinal Health, AmerisourceBergen Drug, McKesson, Walgreens, and CVS as they constitute a significant majority of the opioid pills delivered into CT1 according to the data described in the Expert Report of Craig J. McCann, Ph.D., CFA, App. 9, pp. 3775 and 3845.